

General Comments at the IRIS December Bi-Monthly Meeting

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Agenda

- Stopping Rules Document
- Research
 - Opportunities for NCEA To Promote/Upgrades Science/Quality of Assessments
- Imaginary/Futuristic Step 1 and Step 4 Meetings
- Well Deserved Compliments

STOPPING RULES

Step in IRIS Process		For Studies Published or Accepted for Publication After EPA's Initial Literature Search, EPA will:	For Studies Submitted but Not Yet Accepted for Publication After EPA's Initial Literature Search, EPA will:	For Research in Progress, EPA will:
–	Before public problem formulation meeting	Fully consider the studies in Step 1 draft documents and in Step 4 draft assessment.	Fully consider the studies in Step 1 draft documents (if published in advance of the release of the documents for public comment) and in Step 4 draft assessment.	Review the written research plan and discuss it with the researcher. If the study promises to be critical, EPA may adjust the start of the assessment to accommodate the research plan timeline.
1a	After problem formulation and before Step 1 public meeting	Fully consider the studies in Step 1 draft documents and in Step 4 draft assessment.	Fully consider the studies in Step 1 draft documents (if published in advance of the release of the documents for public comment) and in Step 4 draft assessment.	Review the written research plan and determine whether delay is warranted. The research must promise to be a highly critical addition to the existing data.
1b, 2, 3	After Step 1 public meeting and before release of Step 4 public comment draft	Review the studies for pertinence and quality. From this step forward, new studies that have been accepted for publication will be considered in a manner that does not delay the assessment development and review process. The use of new studies in the assessment will be discussed in the LitSearch section. If added to the assessment after Steps 2 or 3, those steps need not be repeated. Step 2 and 3 reviewers will be informed of the implications of the new studies, as appropriate.	<p>At this point, EPA will no longer consider studies unless they have been accepted for publication as described at left.</p> <p>It is expected that research in progress will have been discussed prior to the Step 1 public meeting.</p>	
4a	After release of public comment draft and before release of peer review draft	Review the studies for pertinence and quality. The study may be added to the peer review draft without repeating earlier steps.		
4b	After release of peer review draft and before peer review meeting	Review the studies for pertinence, quality, and impact on the conclusions. EPA will present its determination orally at the peer review meeting. The study will be added to the assessment if recommended in the Final Peer Review Report by the peer review panel.		

Stopping Rules Need Revision

- Stopping Rules (SR) document intended to serve useful purpose to control when new information will be considered and not delay progress
- As written, gives some “misimpressions” but more importantly, could be interpreted to limit opportunity/interest to upgrade the science

Some Concerns:

- Published/Unpublished
- Research

Stopping Rules: Published/Unpublished

Impression given that EPA will only rely only on publications published, accepted and (perhaps) submitted

While journal publication is important, should not be a condition precedent to EPA's use

Note: Recognizes this may not have been EPA's intent and that the IRIS Office will (and has) used unpublished studies (recent Evidence Tables)

If correct, why not reflect this in a revised SR document.

Stopping Rules: Research

SR can be misinterpreted to give impression that the IRIS program does not care much about research. SR document says:

- After Step 1 meeting: “EPA will no longer consider studies unless they have been accepted for publication”

SR does not take into consideration that Step 1 meeting might identify uncertainties, data needs that could significantly reduce the uncertainties and enhance the quality of the subject chemical assessment and/or even a broader topic.

Also, studies/data generated may not get submitted for publication

Imagine: Stakeholder Meeting #5

IMAGINE: Step1 Meeting

IRIS Office presents preliminary evaluation including:

- Problem Formulation (if not previously presented) and/or updates since Meeting #3 (or last time EPA presented)
- Key features/observations from expanded, qualitative and qualitative Evidence Tables including preliminary take on:
 - Endpoints of likely concern and associated key studies
 - Uncertainties/limitations thus far identified
 - Possible ways to address uncertainties/limitations including research initiatives both short and longer term potentially extending beyond the timeline for the current IRIS assessment
 - Science-policy issues that need to get sorted out and approaches being considered
 - How the issues on subject chemical might relate to other chemicals and/or other things going on

IMAGINE: Step1 Meeting

EPA's preliminary perspectives on what commenters had to say, as a lead in to a robust dialogue including:

- Changes being considered based on comments
- New issues that might need to be revisited
- Questions/confusions that need clarification

NOTE: A larger room might be needed because Stakeholders will be interested in hearing discussions first-hand EPA's views Academics will be there to get insight into research that they might want to undertake (and maybe funding).

Imagine: Step 4 Meeting

New Format, which was adopted during Stakeholder Meeting #5

Rather than Stakeholders present a summary of their written comments, EPA would start by presenting not just an overview of the draft assessment, but allocate more attention to:

- Highlights from public comments received, including preliminary views on:
 - Issues EPA intends (or is considering) revisiting before peer review
 - Issues EPA is not inclined to address and why
 - Issues EPA did not fully understand/needs further discussion
 - Issues that trigger policy/ broader consideration that are cross cutting (e.g., pooling epi data)
- EPA preliminary plans for next steps

Well-Deserved Compliments